510(k) Summary

AUG 10 2012

Trade Name: Scepter C Occlusion Balloon Catheter
Scepter XC Occlusion Balloon Catheter

Generic Name: Occlusion Balloon Catheter

Classification: Class II

MJN, 21 CFR 870.4450 (Vascular Clamp)
DQY, 21 CFR 870.1250 (Percutaneous Catheter)

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California U.S.A.

Date: June 15, 2012

Contact: Naomi Gong

Predicate Device:

510(k) Number	Description	Clearance Date
K110741	Scepter C Occlusion Balloon Catheter	Sep 29, 2011
K113698	Scepter XC Occlusion Balloon Catheter	Jan 13, 2012
K083343	Headway 17 Microcatheter	Dec 4, 2008

Device Description:

The Scepter C and XC Occlusion Balloon Catheter is a dual coaxial lumen catheter with a non-detachable low inflation pressure compliant balloon attached to the distal end of the catheter. The catheter is designed to track over a steerable guidewire. The inner lumen can be used for infusion/delivery of diagnostic and therapeutic agents. The outer lumen is used for the inflation and deflation of the balloon independent of guidewire position. Radiopaque marker bands are located at ends of the balloon and distal tip of the catheter to facilitate fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories. The catheters are packaged sterile for single use only.

Indications For Use:

It is intended for use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms.

It is intended for use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.

It is intended for neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter C/XC Balloon Catheter."

Verification and Test Summary:

Pre-clinical Testing	**Result**
Visual Inspection	Pass
Tensile strength	Pass
Leakage (liquid and air)	Pass
Static and dynamic burst pressure	Pass
Simulated use	Pass
Catheter flexural fatigue	Pass
Compatibility with diagnostic and therapeutic agents Delivery of embolization materials (i.e. Onyx®)	Pass
Balloon testing – burst, compliance, deflation time, fatigue	Pass
DMSO Compatibility	Pass
Bicompatibility testing: Cytotoxcitiy (ISO 10993-5) - MEM elution assay Sensitization/Irritation (ISO 10993-10) - Guinea pig maximization sensitization - Intracutaneous reactivity Hemocompatibility (ISO 10993-4) - Hemolysis - UPTT - Complement activation C3a and SC5b-9 - 4 hour thromboresistance in dogs Systemic Toxicity (ISO 10993-11) - Systemic toxicity - Rabbit pyrogen test	Pass

Scepter C and Scepter XC have been verified to be compatible for use with diagnostic agents (such as contrast media) and liquid embolic devices (such as Onyx® liquid embolic systems).

Technological Comparison:

	Predicate Device Scepter C/XC (K110741/K113698)	**Predicate Device** Headway 17 (K083343)	**510(k) Subject Device**
Intended Use	For use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and also offers balloon assisted embolization of intracranial aneurysms.	For general intravascular use, including the peripheral, coronary, and neurovasculature, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	For use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and also offers balloon assisted embolization of intracranial aneurysms. For general intravascular use, including the peripheral and neurovasculature, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.
Lumen configuration	Dual coaxial lumen	Single lumen	Same as Scepter C/XC
Inner Center Lumen Diameter	0.0165"	0.017"	Same as Scepter C/XC
Outer Diameter	2.6 – 2.8F		Same as Scepter C/XC
Balloon Diameter/Length	4 mm/ 10-20 mm	N/A	Same as Scepter C/XC
Material	Polyether block amide, polyolefin, stainless steel, PTFE, polyurethane elastomeric alloy, Pt alloy, polypropylene		Same as Scepter C/XC
Introducer sheath	N/A	Yes	Yes
Shaping Mandrel	N/A	Yes	Yes
Distal tip shaping	N/A	Yes	Yes
Guidewire compatibility	0.014" wire or smaller	Same	Same
Method of supply	Sterile and single use	Same	Same

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the Scepter C and XC Occlusion Balloon Catheter when compared with the predicate devices, Scepter C/XC Occlusion Balloon Catheter (K110741/K113698) and Headway 17 (K083343).

The devices:
- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are sterilized using same methods and processes.

In summary, the Scepter C and XC Occlusion Balloon Catheters described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Micro Vention, Inc.
% Naomi Gong
1311 Valencia Avenue
Tustin, CA 92780 US

Re: K121785
Trade/Device Name: Scepter C and XC occlusion balloon catheters
Regulation Number: 21 CFR 870.4450
Regulation Name: Occlusion Balloon Catheter
Regulatory Class: Class II
Product Code: MJN, DQY
Dated: June 15, 2012
Received: June 18, 2012

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

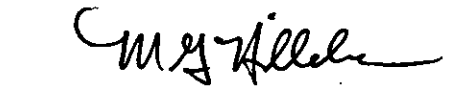
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MicroVention, Inc.

Indications for Use

510(k) Number (if known): K121785

Device Name: Scepter C Occlusion Balloon Catheter
Scepter XC Occlusion Balloon Catheter

Indications For Use:

For use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms.

For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.

For neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter C/XC Balloon Catheter.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121785